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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

10177-141-999

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

09/816,832

Filed

3/22/01

First Named Inventor

Mueller et al.

Art Unit

3739

Examiner

David M. Shay

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒ attorney or agent of record. 54,390  
Registration number \_\_\_\_\_

☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

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Telephone number

12/27/05

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 10177-141-999  
CAM: 008563-999139

Group Art Unit: 3739 )  
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Examiner: David M. Shay )  
)  
Inventor: Mueller, et al. )  
)  
Serial No.: 09/816,832 )  
)  
Filed: March 22, 2001 )  
)  
For: PHOTOATHEROLYTIC )  
CATHETER )  
APPARATUS AND METHOD )  
)

**PRE-APPEAL BRIEF  
CONFERENCE REQUEST**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby request review of the Final Rejection mailed September 22, 2005 ("Final Rejection") of the above-captioned application prior to filing an appeal brief for the reasons set forth below. Applicants submit that the Final Rejection fails to establish a *prima facie* rejection.

**I. PROSECUTION SUMMARY**

Independent claim 1 and its dependent claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,019,075 to Spears *et al.* ("Spears"), in combination with U.S. Patent No. 5,700,243 to Narciso, Jr. ("Narciso") and U.S. Patent No. 6,033,645 to Unger *et al.* ("Unger"). Claim 2, which depends from claim 1, has been rejected under 35 U.S.C. § 103(a) based on Spears, Narciso, and U.S. Patent No. 5,445,608 to Chen *et*

*al.* (“Chen”). Independent claim 6 and its dependent claims 7-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Spears in combination with Narciso.<sup>1</sup>

Claim 1 recites the steps of advancing a catheter over a guidewire, “removing the guidewire from the catheter, [and] introducing through the catheter a fiber-optic bundle...wherein the fiber optic bundle is slidably associated with the catheter lumen.”

Claim 6 similarly recites a guidewire, a catheter, and “a fiber-optic bundle...being adapted for introduction into and slidably associated with the catheter lumen after the catheter’s distal end sleeve is positioned within the target region, and the guidewire is removed.” In short, in the present invention, a guidewire is inserted, a catheter is inserted over the guidewire, the guidewire is removed, and the fiber-optic bundle is inserted into the catheter.

## **II. FAILURE TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS**

A *prima facie* case of obviousness has not been made with regard to independent claims 1 and 6 and their dependent claims because the cited art, namely Spears and Narciso<sup>2</sup> fails to describe each and every claim element of claims 1 and 6.

The Examiner has indicated that Narciso does not teach, disclose or suggest a fiber-optic bundle slidably associated with a catheter (*see, e.g.*, Final Rejection at 4). Instead, Narciso teaches a fiber-optic bundle integral with the catheter (Narciso at column 2, lines 14 to 18). The Examiner erroneously relies on Spears to cure the deficiencies of Narciso. Specifically, the Examiner stated in the Final Rejection, “a careful reading of Spears, for example column 9, lines 19 to 27 and lines 36 to 41 and lines 62 to 65. All discuss the use of a guide wire sometimes in conjunction with optical fiber.” (Final Rejection at 2). None of

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<sup>1</sup> Applicants further note that claims 10-15 are also pending in the above-captioned application, but are not discussed herein. Claims 14-15 have been allowed. The lack of discussion of claims 10-13 herein in no way represents an acquiescence by Applicants of the Examiner’s rejection of claims 10-13.

<sup>2</sup> Unger is cited for its purported disclosure of injecting a contrast fluid and a light-transmissive fluid. Chen is cited for its purported disclosure of a hematoporphyrin derivative as a photodynamic therapy compound. Without addressing the merits of the Examiner’s statements, Applicants do not discuss Unger and Chen, as they are not relevant to the pertinent claim recitations discussed herein.

these passages teach, describe or suggest a fiber-optic bundle slidably associated with a catheter after the removal of a guidewire:

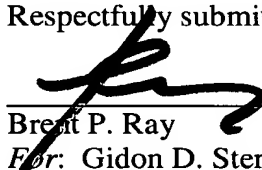
- Column 9, lines 19 to 27 of Spears discloses a hollow optical fiber, wherein a guidewire is inserted into the fiber during laser energy transmittal. This teaches away from claims 1 and 6, as this passage describes a guidewire inserted *after* the optical fiber.
- Column 9, lines 36 to 41 of Spears discloses using electrical conductors 64 as a guidewire *instead of* utilizing fiber optics. Again, this passage does not teach using a guidewire and fiber optic bundle in succession.
- Column 9, lines 62 to 65 of Spears discloses inserting a balloon 34 over a guidewire, but says *nothing* about fiber optics, and further omits any teaching or suggestion of removing the guidewire.

The Examiner has also erroneously indicated that the requisite disclosure of a fiber-optic bundle slidably associated with a catheter after the removal of a guidewire allegedly appears at column 8, lines 31 to 45 of Spears. Specifically, the Examiner appears to consider the phrase “the usual guide wire is replaced with an optical fiber 30” as teaching the insertion of a fiber optic bundle following the removal of a guidewire. Notably, while Spears states that the guide wire is “replaced” with an optical fiber, there is no teaching or suggestion that the replacement involves the successive removal of the guidewire and introduction of the fiber optic bundle after removal of the guide wire. Instead, it is very clear from the specification that this passage does not mean removal of the guidewire during use of the device. Earlier in column 8 at lines 4-14, Spears discusses the prior art “conventional procedure” of inserting a catheter 20 over a guidewire 10. (*See also* Spears at Figs. 1A-1D). Then, when referring to Fig. 2 at lines 31-45 of column 8, Spears states that “the usual guide wire is replaced with an optical fiber 30.” Reading the column 8 continuously, it is therefore clear that Spears is not disclosing the physical acts of removing a guidewire, and thereafter

inserting a fiber optic bundle. Rather, the word "replaced" refers to the use of an optical fiber 30 in Figure 2 *instead of* the conventional guide wire 10 described in relation to Figs. 1A-1D. This is entirely consistent with the later-described embodiments in Spears. (*See, e.g.*, Spears at column 9, lines 36 to 41). Thus, Spears does not cure the deficiencies of Narciso.

The Examiner does not cite, and Applicants cannot find, any teaching, description, or suggestion of a fiber-optic bundle slidably associated with a catheter after the removal of a guidewire in Spears, nor in any reference of record.

For at least the above reasons, Applicants submit that independent claims 1 and 6 are in condition for allowance. As claims 2-5 depend from independent claim 1, and claims 7-9 depend from independent claim 6, Applicants submit these claims are likewise in condition for allowance.

Date:	<u>December 27, 2005</u>	Respectfully submitted,	
			
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